

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Gary L. GRIFFITHS et al.  
Title: METHODS AND COMPOSITIONS FOR INCREASING THE  
TARGET-SPECIFIC TOXICITY OF A CHEMOTHERAPY DRUG  
Appl. No.: Unassigned  
Filing Date: 02/06/2002  
Examiner: Unassigned  
Art Unit: Unassigned



**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
Box PATENT APPLICATION  
Washington, D.C. 20231

Sir:

Applicants submit herewith on Form PTO-1449 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 09/399,221, filed 09/17/1999. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date February 6, 2002

FOLEY & LARDNER  
Customer Number: 22428



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By

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Form PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 018733-1089	SERIAL NO. Unassigned
<b>INFORMATION DISCLOSURE CITATION</b>  (Use several sheets if necessary)		APPLICANT Gary L. GRIFFITHS et al.	
		FILING DATE 02/06/2002	GROUP ART UNIT Unassigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	A1	3,927,193	12/16/1975	Hansen et al			
	A2	4,331,647	05/25/1982	Goldenberg			
	A3	4,348,376	09/07/1982	Goldenberg			
	A4	4,361,544	11/30/1982	Goldenberg			
	A5	4,468,457	08/28/1984	Goldenberg et al.			
	A6	4,444,744	04/24/1984	Goldenberg			
	A7	4,460,459	07/17/1984	Shaw et al.			
	A8	4,460,561	07/17/1984	Goldenberg			
	A9	4,036,945	07/19/1977	Haber			
	A10	4,735,210	04/05/1988	Goldenberg			
	A11	5,851,527	12/22/1998	Hansen			

## FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
							YES	NO
	A12	91/09134	06/27/1991	WIPO				
	A13	0 501 215 A2	02/10/1992	EPO				
	A14	96/20011	07/04/1996	WIPO				
	A15	97/41898	11/13/1997	WIPO				
	A16	99/42593	08/26/1999	WIPO				
	A17	99/66951	12/29/1999	WIPO				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	A18	TRAIL ET AL., "Cure of Xenografted Human Carcinomas by BR96-Doxorubicin Immunoconjugates", Science, 1993, pp. 212-215, Vol. 261.
	A19	TRAIL ET AL., "Effect of Linker Variation on the Stability, Potency, and Efficacy of Carcinomareactive BR64-Doxorubicin Immunoconjugates", Cancer Res., 1997, pp. 100-105, Vol. 57.
	A20	ARCAMONE, "Properties of Antitumor Anthracyclines and New Developments in Their Application: Cain Memorial Award Lecture", Cancer Res., 1985, pg. 5995, Vol. 45.

EXAMINER

DATE CONSIDERED

\* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include any copy of this form with next communication to applicant.

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<b>OTHER DOCUMENTS</b> (Including Author, Title, Date, Pertinent Pages, Etc.)							
	A21	POTTER ET AL., "Isolation and Partial Characterization of a cDNA Encoding a Rabbit Liver Carboxylesterase That Activates the Prodrug Irinotecan (CPT-11)", Cancer Res., 1998, pp. 2646-2651, Vol. 58.					
	A22	POTTER ET AL., "Cellular Localization Domains of a Rabbit and Human Carboxylesterase: Influence on Irinotecan (CPT-11) Metabolism by the Rabbit Enzyme", Cancer Res., 1998, pp. 3627-3632, Vol. 58.					
	A23	WANG ET AL., "Specific Activation of Glucuronide Prodrugs by Antibody-Targeted Enzyme Conjugates for Cancer Therapy", Cancer Res., 1992, pp. 4484-4491, Vol. 52.					
	A24	BAKINA ET AL., "Intensely Cytotoxic Anthracycline Prodrugs: Glucuronides", J. Med Chem., 1997, pp. 4013-4018, Vol. 40.					
	A25	SCHMIDT ET AL., "Glucuronide Prodrugs of Hydroxy Compounds For Antibody Directed Enzyme Prodrug Therapy (Adept) A Phenol Nitrogen Mustard Carbamate", Bioorg. Med Chem. Lett., 1997, pp. 1071-1076, Vol. 7.					
	A26	GUPTA ET AL., "Pharmacokinetic Modulation of Irinotecan and Metabolites by Cyclosporin A", Cancer Res., 1996, pp. 1309-1314, Vol. 56.					
	A27	GUPTA ET AL., "Modulation of Glucuronidation of SN-38, The Active Metabolite of Irinotecan, by Valproic Acid and Phenobarbital", Cancer Chemother. Pharmacol., 1997, pp. 440-444, Vol. 39.					
	A28	MELTON ET AL., "Antibody-Directed Enzyme Prodrug Therapy (ADEPT) Review Article", Drugs of the Future 1996, pp. 167-181, Vol. 21, No. 2, Barcelona, Spain.					
	A29	HAY ET AL., "Antibody-Directed Enzyme Prodrug Therapy (ADEPT)", Drugs of the Future, 1996, pp. 917-931, Vol. 21, No. 9.					
	A30	TAKAYAMA ET AL., "Synthesis of a New Class of Camptothecin Derivatives, The Long-Chain Fatty Acid Esters of 10-Hydroxycamptothecin, as a Potent Prodrug Candidate, and Their In Vitro Metabolic Conversion by Carboxylesterases", Bioorganic & Medicinal Chemistry Letters, 1998, pp. 415-418, Vol. 8, No. 5, Oxford, Great Britain.					
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>			
* <b>EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include any copy of this form with next communication to applicant.							

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<b>OTHER DOCUMENTS</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	A31	DANKS ET AL., "Comparison of Activation of CPT-11 by Rabbit and Human Carboxylesterases for Use in Enzyme/Prodrug Therapy", Clinical Cancer Research, 1999, pp. 917-924, Vol. 5, No. 4.					
	A32	LEU ET AL., "Design and Synthesis of Water-Soluble Glucuronide Derivatives of Camptothecin for Cancer Prodrug Monotherapy and Antibody-Directed Enzyme Prodrug Therapy (ADEPT)", Journal of Medicinal Chemistry, 1999, pp. 3623-3628, Vol. 42, No. 18.					
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